

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

IN RE: DIET DRUGS (PHENTERMINE/	:	MDL DOCKET NO. 1203
FENFLURAMINE/DEXFENFLURAMINE)	:	
PRODUCTS LIABILITY LITIGATION	:	
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THIS DOCUMENT RELATES TO:	:	CIVIL ACTION
	:	NO. 99-20593
SHEILA BROWN, ET AL.	:	
	:	
v.	:	
	:	
AMERICAN HOME PRODUCTS	:	
CORPORATION	:	
<hr/>		
BONNIE ELAINE THURBER LU	:	
Plaintiff	:	
	:	CIVIL ACTION NO.
v.	:	2:02-CV-20147 HB
	:	
AMERICAN HOME PRODUCTS CORPORATION,	:	
ET AL.,	:	
Defendants.	:	
	:	

**REPORT AND RECOMMENDATION NO. 20 OF SPECIAL MASTER
(AS TO MOTION TO ENFORCE PARAGRAPH 7 OF PRETRIAL ORDER
NO. 1415 AGAINST ELAINE LU)**

I. INTRODUCTION

Wyeth has filed a Motion to Enforce Pretrial Order No. 1415 ("Wyeth's Motion") and an accompanying memorandum ("Wyeth's Memorandum") against Plaintiff, Elaine Lu ("Plaintiff"). In its Motion, Wyeth seeks an order directing Plaintiff to dismiss her Primary Pulmonary Hypertension ("PPH") claim. Pursuant to Paragraph 1 of Pretrial Order No. 2383, Wyeth's Motion was referred to me.

Upon consideration of Wyeth's Motion and Plaintiff's Response, I have determined that Plaintiff's claim is a Settled Claim, as that term is defined in Section I.53 of the Nationwide Class Action Settlement Agreement with American Home Products Corporation ("Settlement Agreement"). Thus, I recommend that Plaintiff be barred and enjoined from asserting her current PPH claim against Wyeth or any other Released Party. I also recommend that the Court enter an order dismissing Plaintiff's current PPH action against Wyeth. Finally, because I do not believe that additional remedies as permitted by Paragraph 9 of Pretrial Order No. 2383 are warranted, I recommend denial of Plaintiff's request to deny Wyeth's Motion as untimely.

II. BACKGROUND

A. Settlement Agreement

On August 28, 2000, the Honorable Louis C. Bechtle entered Pretrial Order No. 1415, certifying a nationwide class and approving the Settlement Agreement pursuant to Federal Rule of Civil Procedure 23. See Pretrial Order No. 1415. Under Pretrial Order No. 1415, Class Members who have failed to exercise an opt-out are barred and enjoined from asserting "Settled Claims" against Wyeth or any other Released Party.¹ See Pretrial Order No. 1415,

¹ Under the Settlement Agreement, Class Members could opt-out of the Settlement and pursue their claims in the tort system by (continued...)

¶ 7. The term "Settled Claims" means:

any and all claims, including assigned claims, whether known or unknown, asserted or unasserted, regardless of the legal theory, existing now or arising in the future by any or all members of the Settlement Class arising out of or relating to the purchase, use, manufacture, sale, dispensing, distribution, promotion, marketing, clinical investigation, administration, regulatory approval, prescription, ingestion, and labeling of Pondimin® and/or Redux™, alone or in combination with any other substance, including, without limitation, any other drug, dietary supplement, herb, or botanical.

See Settlement Agreement, § I.53, at 12.² Settled Claims, however, do not include those claims based on qualifying diagnoses of PPH:

Notwithstanding the foregoing, Settled Claims do not include claims based on PPH, including claims for compensatory, punitive, exemplary or multiple damages based on PPH; provided, however, that if a Class Member receives settlement benefits from Fund B, he/she may not bring a lawsuit based upon a claim for PPH, unless the Class Member was diagnosed with PPH before the Class Member had left-sided heart valve abnormalities (other than those which produce trivial, clinically insignificant left-sided regurgitation) or Endocardial Fibrosis. . . .

Settlement Agreement, § I.53, at 13 (emphasis added). For purposes of determining whether a plaintiff is pursuing a non-settled PPH claim, the term "PPH" is defined as follows:

- a. For a diagnosis based on examinations and clinical findings prior to death:

¹(...continued)
exercising the initial, intermediate, or back-end opt-out right.
See Settlement Agreement, § IV.D.

² All definitions and terms of the Settlement Agreement were adopted by the Court in Pretrial Order No. 1415. See Pretrial Order No. 1415, ¶ 1.

- (1) (a) Mean pulmonary artery pressure by cardiac catheterization of \geq 25 mm Hg at rest or \geq 30 mm Hg with exercise with a normal pulmonary artery wedge pressure \leq 15 mm Hg; or
- (b) A peak systolic pulmonary artery pressure of \geq 60 mm Hg at rest measured by Doppler echocardiogram utilizing standard procedures; or
- (c) Administration of Flolan to the patient based on a diagnosis of PPH with cardiac catheterization not done due to increased risk in the face of severe right heart dysfunction; and

(2) Medical records which demonstrate that the following conditions have been excluded by the following results:

- (a) Echocardiogram demonstrating no primary cardiac disease including, but not limited to, shunts, valvular disease (other than tricuspid or pulmonary valvular insufficiency as a result of PPH or trivial, clinically insignificant left-sided valvular regurgitation), and congenital heart disease (other than patent foramen ovale); and
- (b) Left ventricular dysfunction defined as LVEF $<$ 40% defined by MUGA, Echocardiogram or cardiac catheterization; and
- (c) Pulmonary function tests demonstrating the absence of obstructive lung disease (FEV/FVC $>$ 50% of predicted) and the absence of greater than mild restrictive lung disease (total lung capacity $>$ 60% or predicted at rest); and
- (d) Perfusion lung scan ruling out pulmonary embolism; and
- (e) If, but only if, the lung scan is indeterminate or high probability, a

pulmonary angiogram or a high resolution angio computed tomography scan demonstrating absence of thromboembolic disease; and

- (3) Conditions known to cause pulmonary hypertension including connective tissue disease known to be causally related to pulmonary hypertension, toxin induced lung disease known to be causally related to pulmonary hypertension, portal hypertension, significant obstructive sleep apnea, interstitial fibrosis (such as silicosis, asbestosis, and granulomatous disease) defined as greater than mild patchy interstitial lung disease, and familial causes, have been ruled out by a Board-Certified Cardiologist or Board-Certified Pulmonologist as the cause of the person's pulmonary hypertension.

-OR-

b. For a diagnosis made after the individual's death:

- (1) Autopsy demonstrating histopathologic changes in the lung consistent with primary pulmonary hypertension and no evidence of congenital heart disease (other than a patent foramen ovale) with left-to-right shunt, such as ventricular septal defect as documented by a Board-Certified Pathologist; and
- (2) Medical records which show no evidence of alternative causes as described above for living persons.

Id., § I.46, at 8-10 (citations omitted). Plaintiffs may assert PPH claims against Wyeth or any other Released Party only if their diagnoses meet the specific criteria of this definition.³

³ On January 4, 2002, the Court entered Pretrial Order No. 2337, which solicited comments and/or objections to a proposed Pretrial Order for resolving Motions to Enforce Pretrial Order No. 1415. See Pretrial Order No. 2337. Various parties submitted (continued...)

B. The Parties' Arguments

In its Motion, Wyeth seeks to enforce the injunction in Paragraph 7 of Pretrial Order No. 1415, which bars and enjoins Class Members who do not exercise their opt-out rights from pursuing Settled Claims. See Pretrial Order No. 1415, ¶ 7. Wyeth contends that Plaintiff's medical condition does not meet the definition of PPH in Section I.46.a of the Settlement Agreement. In particular, Wyeth argues that Plaintiff's condition does not meet any of the three subparts of Part 1 of the PPH definition. See Wyeth's Memorandum at 3-5.⁴

1. Part 1(a) of the PPH Definition

Wyeth argues that Plaintiff's medical records contain

³(...continued)
objections and/or modifications to the proposed Pretrial Order. The Objectors challenged, among other things: (1) the jurisdiction and authority of the Court to enforce Paragraph 7 of Pretrial Order No. 1415; (2) the definition of PPH, as outlined in the Settlement Agreement; (3) the time limitations in enforcing Paragraph 7 of Pretrial Order No. 1415; (4) the burden of proof or persuasion in enforcing Paragraph 7 of Pretrial Order No. 1415; and (5) the imposition of sanctions on parties. On January 28, 2002, Wyeth responded to the objections.

On January 30, 2002, the Court heard oral arguments from counsel for Wyeth, Class Counsel to the Settlement Class, and various Objectors to the proposed Pretrial Order. Thereafter, on February 26, 2002, the Court entered Pretrial Order No. 2383, which established the procedure for resolving Motions to Enforce Paragraph 7 of Pretrial Order No. 1415 against Class Members asserting alleged PPH claims against Wyeth or any other Released Party. See Pretrial Order No. 2383.

⁴ In its Motion, Wyeth argues that Plaintiff fails to satisfy Part 3 of the PPH definition. Wyeth later withdrew this argument.

measurements of pulmonary capillary wedge pressure ("wedge pressure")⁵ greater than 15 mm Hg in three separate cardiac catheterizations. These wedge pressure measurements surpass the minimum required to satisfy Part 1(a) of the PPH definition. See Wyeth's Memorandum at 4. Specifically, Wyeth identifies measurements contained in the medical records reflecting Plaintiff's cardiac catheterizations on: (1) March 11, 2001 (wedge pressure measurement of 18-20 mm Hg); (2) April 23, 2001 (wedge pressure measurement of 16-18 mm Hg); and (3) December 28, 2001 (wedge pressure measurement of 20 mm Hg). See id.; see also Wyeth's Reply to Plaintiff's Memorandum in Response to Wyeth's Motion ("Wyeth's Reply") at 3.

In response, Plaintiff argues that in the opinion of her cardiologist, the wedge pressure measurement from her April 23, 2001 cardiac catheterization satisfies the PPH definition. See Plaintiff's Memorandum in Response to Wyeth's Motion ("Plaintiff's Response") at 7. Specifically, Plaintiff contends that Rodney S. Badger, M.D., her cardiologist for her April 23, 2001 catheterization, recorded in Plaintiff's catheterization report that she had a "normal ... wedge pressure." Dr. Badger also testified during his deposition that Plaintiff's wedge pressure was 10 mm Hg. See id. at 7; Exhibit 9 at 3; Exhibit 8 at 29, 31, 45,

⁵ For purposes of the PPH definition, a pulmonary capillary wedge pressure measurement is the same as a pulmonary artery wedge pressure measurement.

53 - 55.

Plaintiff also argues that she meets the PPH definition through the opinion of Lewis Rubin, M.D., who examined Plaintiff and reviewed her medical records. See Plaintiff's Response at 9. In Dr. Rubin's opinion, Plaintiff has PPH even though she has a wedge pressure in excess of 15 mm Hg. See id. at 10.

Wyeth argues, in response, that Dr. Badger never recorded a wedge pressure measurement of 10 mm Hg during Plaintiff's catheterization. See Wyeth's Reply at 2. Further, Wyeth points to Dr. Badger's deposition testimony, wherein he answers the following questions related to Plaintiff's wedge pressure during the April 23, 2001 catheterization:

Q: Am I correct that on that page of the exhibit there were wedge pressure readings taken at three different points in time?

A: Correct.

Q: And the first one refers, indicates the wedge pressure reading was 18 and the second 16 and the third 17?

A. That's right.

....

Q: Have you ever recorded a number that you thought was her wedge pressure, as measured by this catheterization, of less than 16?

A: I have not written or dictated a number less than 16, no.

Id. at 3 (citations omitted). Wyeth further argues that during his deposition, Dr. Badger "attempted to change his story, claiming that plaintiff's wedge pressure was actually 10 mm Hg instead of

the 16 mm Hg value he wrote down in her medical records." Id. at 4. Wyeth contends that Dr. Badger's medical records, not his contradictory testimony, should control. See id. at 4.

Wyeth, also, discounts the opinion of Dr. Rubin and argues that, pursuant to Pretrial Order No. 2793, the PPH definition contained in the Settlement Agreement controls and a doctor, therefore, cannot "explain away" the wedge pressure requirement under the Settlement Agreement. See id. at 5.

2. Part 1(b) of the PPH Definition

Wyeth next argues that Plaintiff's peak systolic pulmonary artery pressure ("PASP") reading does not equal or surpass 60 mm Hg, which is the minimum requirement under Part 1(b) of the PPH definition. See Wyeth's Memorandum at 5. Specifically, Wyeth states that on November 30, 2000, Plaintiff's PASP measurement was 55 mm Hg. See id. Plaintiff presents no argument concerning Part 1(b).

3. Part 1(c) of the PPH Definition

Finally, Wyeth argues that Plaintiff has not provided any evidence that she has been administered Flolan, as required to satisfy Part 1(c) of the PPH definition. See Wyeth's Memorandum at 5. Plaintiff presents no argument concerning Part 1(c).

Following briefing of these issues, I heard oral argument.⁶

⁶ For the Court's convenience, I am forwarding copies of the parties' submissions and the transcript of the teleconference related to this matter. After oral argument, the parties submitted (continued...)

In addition to hearing arguments related to Part 1 of the PPH definition, the parties argued whether Wyeth filed its Motion in a timely fashion. See Special Master Teleconference Transcript at 15-18.

III. RECOMMENDATION

In my view, Plaintiff has failed to establish that her medical condition meets Part 1 of Section I.46.a of the PPH definition in the Settlement Agreement. See Settlement Agreement, § I.46.a(1) at 8. First, the medical records for Plaintiff's cardiac catheterization fail to show a wedge pressure measurement of less than or equal to 15 mm Hg, as required by Part 1(a). In fact, these records reflect: (1) a wedge pressure measurement of 18-20 mm Hg on March 11, 2001; (2) a wedge pressure measurement of 16 mm Hg or greater on April 23, 2001; and (3) a wedge pressure measurement of 20 mm Hg on December 28, 2001.

Second, in my view, Plaintiff cannot satisfy Part 1(a) of the PPH definition through Dr. Badger's opinions and testimony which contradict the medical records. In particular, Dr. Badger's non-specific determination that Plaintiff's wedge pressure was "normal"

⁶(...continued)
correspondence regarding, inter alia, the adjudicatory nature of the Pretrial Order No. 2383 process. See Correspondence from Sharon J. Arkin, Esquire to Gregory P. Miller, Esquire; Correspondence from Mark J. Spooner, Esquire and Lisa M. Kerr, Esquire to Gregory P. Miller, Esquire.

is insufficient to meet the PPH definition, because he acknowledged observing wedge pressure readings of 16 mm Hg or greater during the catheterization. In addition, although Dr. Badger testified that Plaintiff's wedge pressure was 10 mmHg, this testimony is contrary to the objective measurements taken during Plaintiff's catheterization. See Deposition of Rodney Badger, M.D., at 29:7-20; 31:17-32:5; 45:16-22; 53:9-56:14 (Plaintiff's Response at Exhibit 8). Under these circumstances, I find Dr. Badger's opinion regarding a never documented assessment of Plaintiff's wedge pressure measurement to be insufficient under the PPH definition.⁷

Third, Plaintiff, also, cannot meet the requirements of Part 1(a) of the PPH definition through Dr. Rubin's expert opinion where, as here, he concedes that "the automated, computerized hemodynamics sheet and tracings for [Plaintiff's April 23, 2001 catheterization] indicate individual wedge pressure measurements greater than 15 mm Hg." See Dr. Rubin's Declaration at 5 (Plaintiff's Response at Exhibit 9). In light of this concession, the PPH definition would have to be modified to accept Dr. Rubin's opinion that Plaintiff has PPH. In my view, this cannot be done.

In arriving at this Recommendation, I considered the Court's recent ruling in Pretrial Order No. 3699. I believe that the facts

⁷ Dr. Badger's testimony that Plaintiff's wedge pressure measurement was 10 mm Hg also is undermined by Plaintiff's expert, Dr. Rubin, who opined based upon the same catheterization records, that Plaintiff's wedge pressure measurements were greater than 15 mm Hg.

underlying this case differ from those facts the Court considered in Pretrial Order No. 3699. In Pretrial Order No. 3699, the Court accepted the opinion of a plaintiff's expert as sufficient evidence to satisfy Part 1(a) of the PPH definition. In that case, unlike the instant one, the plaintiff presented a catheterization report which showed that her wedge pressure measurement was 14 to 16 mm Hg. The plaintiff, therefore, provided a catheterization report which demonstrated a measurement within the PPH definition. Based upon what appeared to be a potentially qualifying catheterization report, the Court found that the expert's opinion that the plaintiff's wedge pressure measurement was, in fact, 14 mm Hg was sufficient to allow her to move forward with her claim.

In this case, Plaintiff Lu has not presented any medical records demonstrating a wedge pressure measurement of 15 mm Hg or less. In fact, Plaintiff has presented just the opposite. In the absence of such records, the opinions of Dr. Badger and Dr. Rubin are simply, in my view, insufficient to satisfy the requirements of the Settlement Agreement. Accordingly, Plaintiff has failed to satisfy Part 1(a) of the PPH definition.⁸

Plaintiff has failed to demonstrate that her PPH claim against

⁸ Plaintiff also has failed to provide an echocardiogram report that shows a peak systolic pulmonary artery pressure reading of greater than or equal to 60 mm Hg at rest. Accordingly, Plaintiff fails to satisfy Part 1(b) of the definition. Finally, Plaintiff has not provided any evidence that she was administered Flolan to satisfy Part 1(c) of the PPH definition. Moreover, Plaintiff has undergone a cardiac catheterization; thus, she is ineligible for consideration under Part 1(c) of the PPH definition.

Wyeth is a non-Settled Claim. Thus, I recommend that: (1) Plaintiff be barred and enjoined from pursuing her current PPH claim against Wyeth; and (2) Plaintiff's action against Wyeth be dismissed.

IV. CONCLUSION

Any party wishing to appeal this Report and Recommendation No. 20 must file such an appeal with the Court within eleven (11) days of receipt, as permitted by Paragraph 10 of Pretrial Order No. 2383.

SO RECOMMENDED:

GREGORY P. MILLER, ESQUIRE
SPECIAL MASTER
MILLER ALFANO & RASPANTI P.C.
1818 Market Street, Suite 3402
Philadelphia, PA 19103
(215) 972-6400

Date: November 2, 2004

CERTIFICATE OF SERVICE

I, Maria L. H. Lewis, Esquire, hereby certify that a true and correct copy of Report and Recommendation No. 20 of the Special Master (as to Motion to Enforce Paragraph 7 of Pretrial Order No. 1415 against Elaine Lu) was served by the described method, upon the persons listed below, on this 2nd day of November, 2004:

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Dated: November 2, 2004

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

IN RE: DIET DRUGS (PHENTERMINE/
FENFLURAMINE/DEXFENFLURAMINE)
PRODUCTS LIABILITY LITIGATION : MDL DOCKET NO. 1203

THIS DOCUMENT RELATES TO: : CIVIL ACTION
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SHEILA BROWN, ET AL. :
v. :
AMERICAN HOME PRODUCTS :
CORPORATION :
BONNIE ELAINE THURBER LU :
Plaintiff :
v. : CIVIL ACTION NO.
2:02-CV-20147 HB

AMERICAN HOME PRODUCTS CORPORATION,
ET AL., :
Defendants. :
v.

PRETRIAL ORDER NO.

AND NOW, this ____ day of _____, 2004, it is hereby ORDERED
that Report and Recommendation No. 20 of the Special Master (as to
Motion to Enforce Paragraph 7 of Pretrial Order No. 1415 Against Elaine
Lu) is AFFIRMED.

It is further ORDERED that:

- (1) Wyeth's Motion as to Plaintiff Elaine Lu (Doc. No. 203681)
is GRANTED;
- (2) Plaintiff Elaine Lu is barred and enjoined from prosecuting
her current PPH claims against Wyeth; and
- (3) The above-captioned action as to Plaintiff Lu is dismissed.

BY THE COURT:

J.

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